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10/540,784	06/08/2005	Mark E. Fraley	21301P	9106

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EXAMINER	
MOORE, SUSANNA	
ART UNIT	PAPER NUMBER
1624	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,784	FRALEY, MARK E.	
	Examiner	Art Unit	
	SUSANNA MOORE	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17,19,30 and 31* is/are pending in the application.

4a) Of the above claim(s) *10-17,19,30 and 31* is/are withdrawn from consideration.

5)☒ Claim(s) *5* is/are allowed.

6)☒ Claim(s) *1-4 and 9* is/are rejected.

7)☒ Claim(s) *6-8* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/27/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group (I) in the reply filed on 1/7/2008 is acknowledged. Group I, drawn to pyrazolo[1,5-a]pyrimdines and simple compositions thereof, embraced by claims 1-9 was elected by Applicant with traverse. The traversal is on the ground(s) that 1) "the Examiner based the restriction on the grounds that the present inventions are unrelated," 2) no search burden is present and 3) the citation of the PCT Article 27(1).

This is not found persuasive for the following reasons:

1) Firstly, the Examiner did not state the inventions were unrelated. The Examiner based the restriction on a lack of unity because the special technical feature can be found in the US 5017212 reference. Thus, unity of invention is considered to be lacking.

2) Secondly, restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;
(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

3) Lastly, Applicant cites the PCT Article 27(1), which Applicant understands as "the standards for unity of invention for the instant application during the national phase must not be different from or additional to those utilized by the International Search Authority (ISA) and International Preliminary Examination Authority (IPEA) during the international phase." The standards are not different. However, there is no such requirement that the U.S. national stage Application and the International Application must be prosecuted the same. There is no such bar.

Thus, the requirement is still deemed proper and is therefore made **FINAL**.

Moreover, Applicant states claims 18, 20-29 and 32-36 have been left out of the restriction requirement. However, the preliminary amendment filed on 6/8/2005, shows these claims as cancelled. In summary, there are 20 claims pending and 9 under consideration. Claims 1-8 are compound claims. Claim 9 is a composition claim. This is the first action on the merits. The application concerns some pyrazolo[1,5-a]pyrimidine compounds and simple compositions thereof.

This application contains claims 1-9, drawn to an invention nonelected with traverse in the paper of 1/7/2008. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Substituted pyrazolo[1,5-a]pyrimidines as Tyrosine Kinase Inhibitors.

This is just a suggestion. Please feel free to change the title so that the invention is accurately described.

Claim Objections

Claims 2 and 4 are objected to because of the following informalities: claims 2 and 4 no longer further limit claim 1 based on the restriction requirement. Appropriate correction is required.

Claims 1-4 and 6-9 are objected to because of the following informalities: claims 1-4 and 6-9 have words which are capitalized and should be lower case, e.g., "Said" and "Claims." Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, Applicant employs the terms "unsubstituted or substituted alkyl", "unsubstituted or substituted alkenyl ", " unsubstituted or substituted alkenyl," etc. In pages 16-17 there is a discussion of the concept of substitution. However, this passage fails to list the intended variables, e.g. "alkenyl," "alkynyl," "aryl" or "heterocyclyl" as claimed in claim 1, at the bottom of page 5. Furthermore, a number of examples are given for "alkyl" and "cylcoalkyl" using open terms. What other substituents does Applicant claim? Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999).

Regarding the term "heterocyclic," which is used throughout claim 1, the claims are too broad in that there is no proper support in the Specification for "heterocyclic groups." *In re Wiggins*, 179 USPQ 421.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4 and 9 rejected under 35 U.S.C. 102(b) as being anticipated by Bilodeau et. al. (US 6380203 B1).

The reference teaches compounds of formula (I), wherein R^2, R^3 and R^5= hydrogen, R^4= 4-methoxyphenyl and R^1= bromo. See column 7, lines 4-5. Furthermore, another specie which meets the limitations of claim 1, wherein R^2, R^3 and R^5= hydrogen, R^4= 4-pyrimidinyl and R^1= bromo. See column 7, line 6. The compositions are taught in column 9, lines 58. Thus, said claims are anticipated by Bilodeau et. al.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Mustazza et. al. (J. Heterocyclic Chem., 2001, 38, 1119-1129).

The reference teaches compounds of formula (I), wherein R^2, R^3 and R^5= hydrogen, R^4= 4-ethylaminophenyl and R^1= CN. See page 1121, Scheme 3, compound 19. Thus, said claims are anticipated by Mustazza et. al.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Fraley et. al. (Bioorg. Med. Chem. Lett., 2002, 12, 2767-2770).

The reference teaches compounds of formula (I), wherein R^2, R^3 and R^5= hydrogen, R^4= 4-pyridinyl and R^1= Br. See page 2769, Scheme 2, the compound in the Scheme 2. Thus, said claims are anticipated by Fraley et. al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fraley et. al. (Bioorg. Med. Chem. Lett., 2002, 12, 2767-2770).

The instant Application claims compounds of formula (I), wherein R^2, R^3 and R^5= hydrogen, R^4= 4-methoxyphenyl and R^1= 4-methoxy-3-pyridyl)

The reference teaches compounds of formula (I), wherein R^2, R^3 and R^5= hydrogen, R^4= 4-methoxyphenyl and R^1= 3-pyridyl, see Table 1, page 2768, compound 2d.

The difference between the claimed compound and the reference is the substitution on the pyridyl at the 3-position of the bicycle, hydrogen versus Applicant's 4-methoxy. The reference teaches guidepost which teach the variable at the 4-position of the cyclic ring at the 3-position of the bicycle can be 4-methoxy, see page 2769, Table 2, compound 3e. Thus, the hydrogen and the 4-methoxy are alternatively useable and renders claims 1-4 obvious.

Claims 1-4 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bilodeau et. al. (US 6380203 B1).

The instant Application claims compounds of formula (I) as tyrosine kinase inhibitors, wherein R^2, R^3 and R^5= hydrogen, R^4= 4-methoxyphenyl and R^1= 5-methoxy-3-pyridyl).

The reference teaches compounds of formula (I) as tyrosine kinase inhibitors, wherein R^2, R^3 and R^5= hydrogen, R^4= 4-methoxyphenyl and R^1= 3-pyridyl, see column 10, example 1, lines 43-56.

The difference between the claimed compound and the reference is the substitution on the pyridyl at the 3-position of the bicycle, hydrogen versus Applicant's 5-methoxy. The genus of formula (I) in column 2, teaches that the heterocyclic ring at R^1 can be substituted with hydrogen, alkyl, mono- and dialkylamino, aryl, heterocyclyl, etc. See lines 56-65, in column. Furthermore, the genus also teaches R1 can be alkyl, halo, alkenyl, alkynyl and heteroaryl, see column 2, lines 41-46. Thus, said claims are rendered obvious by Bilodeau et. al.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim1-3 of U.S. Patent No. 6235741. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '741 patent contains obvious variants of the species embraced by the genus of the instant Application. For example, the 10th specie listed in claim 3 of the reference, 3-(3-pyridyl)-6-(4-methoxyphenyl)pyrazolo(1,5-a)pyrimidine is obvious over 3-(4-amino(3-pyridyl))-6-(4-methoxyphenyl)pyrazolo(1,5-a)pyrimidine. The only difference between the two named species is the substitution on the pyridyl ring at the 6-position of the bicycle, the amino substituent at the four position of the pyridyl ring claimed in the instant invention versus hydrogen. The genus in column 2, lines 56 and 59 teaches the variables are alternatively useable. Thus, said claims are rendered obvious by the '741 patent.

Claims 1-9 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim1-3 of U.S. Patent No. 6245759. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '759 patent contains obvious variants of the species embraced by the genus of the instant Application. For example, the 12th specie listed in claim 3 of the reference, 1-(3-dimethylamino-propyl)-4-(3-thiophen-3-yl)pyrazolo(1,5-a)pyrimidin-6-yl-1H-pyridin-2-one is obvious over (3-thiophen-3-yl)pyrazolo(1,5-a)pyrimidin-6-yl-1H-pyridin-2-one. The only difference between the two named species is the substitution on the pyridyl ring at the 6-position of the bicycle, the 3-dimethylamino-propyl versus Applicant's hydrogen. The genus in column 27, line 32, teaches

the two variables are alternatively useable. Thus, said claims are rendered obvious by the '741 patent.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSANNA MOORE whose telephone number is (571)272-9046. The examiner can normally be reached on M-F 8:00-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susanna Moore/
Examiner, Art Unit 1624

/Brenda L. Coleman/
Primary Examiner, Art Unit 1624